ISRCTN63491981 https://doi.org/10.1186/ISRCTN63491981

Clinical study to evaluate the efficacy, safety and kinetics of Octagam® 10% for replacement therapy in primary immunodeficiency diseases

Submission date
05/12/2008

Recruitment status
Stopped

Registration date
18/12/2008

Overall study status
Stopped

Last Edited
30/04/2013

Condition category
Haematological Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00811174

Secondary identifying numbers
GAM10-03

Study information

Scientific Title

Study objectives
Safety of Octagam® 10% in primary immunodeficiency diseases (PID) and comparison of pharmacokinetics of Octagam® 5% and Octagam® 10%.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Albert-Ludwigs-Universität Freiburg Ethik-Kommission gave approval on the 27th October 2008

Study design
Prospective open-label non-controlled non-randomised multi-centre phase III study

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Primary immunodeficiency diseases (PID)

Interventions
30/04/2013: Please note that this study was stopped in October 2010.

Octagam® will be given by intravenous infusion at a constant dose of 300 - 600 mg/kg body weight every 21 (+/- 3) or 28 (+/-3) days for 12 months. Follow-up will be performed 3 or 4 weeks after last infusion.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Octagam® 5%, Octagam® 10%

Primary outcome measure
1. Rate of Octagam® 10% infusions with one or more adverse events occurring during or within 72 hours after end of infusion
2. Comparison of pharmacokinetics of Octagam® 5% and Octagam® 10%

Secondary outcome measures
1. Occurrence of adverse events, measured throughout the study
2. Vital signs, measured during each treatment
3. Safety laboratory measurements, measured at each treatment date (every three to four weeks)
4. Viral safety tests, measured every 3 months
5. Pharmacokinetics of glucose and maltose, measured after 6 months of treatment
6. Rate of serious bacterial infections, measured throughout the study
7. Rate of other infections, measured throughout the study
8. Trough levels and pharmacokinetics of total serum IgG (measured before each treatment), IgG subclasses and antigen specific antibodies (measured before treatment 10 or 12 and at the end of the study)
9. Use of antibiotics, throughout the study
10. Rate of absence from work/school, throughout the study
11. Number and days of hospitalisation, throughout the study

Overall study start date
01/01/2009

Completion date
01/06/2010

Reason abandoned (if study stopped)
Objectives no longer viable

Eligibility

Key inclusion criteria
1. Age of greater than or equal to 2 years and less than or equal to 75 years, either sex
2. For minor patients, above a minimum weight based on the amount of blood required for testing: per individual, the trial-related blood loss (including any losses in the manoeuvre) should not exceed 3% of the total blood volume during a period of four weeks and should not exceed 1% at any single time (the total volume of blood is estimated at 80 ml/kg body weight)
3. Confirmed diagnosis of primary immunodeficiency as stated by the World Health Organization and requiring immunoglobulin replacement therapy. The exact type of PID should be recorded.
4. Previously treated with commercial Octagam® 5% every 21 - 28 days for at least six infusion intervals at a constant dose of 300 - 600 mg/kg body weight
5. Availability of the IgG trough levels of the two previous infusions before enrolment, and maintenance of at least 5.5 g/L in the trough levels of these two infusions
6. Negative result on a pregnancy test (human chorionic gonadotropin [HCG]-based assay in blood or urine) for women of child-bearing potential and use of a reliable method of contraception for the duration of the study

7. For adult patients: freely given written informed consent. For minor patients: freely given written informed consent from both parents/legal guardians and written informed assent from the child/adolescent greater than or equal to 8 years of age according to his/her age and capacity of understanding
8. Willingness to comply with all aspects of the protocol, including blood sampling, for the duration of the study

Participant type(s)
Patient

Age group
Other

Sex
Both

Target number of participants
45

Key exclusion criteria
1. Acute infection requiring intravenous antibiotic treatment within two weeks before screening
2. Known history of adverse reactions to IgA in other products
3. Exposure to blood or any blood product or derivative, other than commercially available Octagam® 5%, within the past 3 months
4. Ongoing history of hypersensitivity or persistent reactions to blood or plasma derived products, or any component of the investigational product, such as maltose
5. Requirement of any routine premedication for IGIV infusion
6. History of congenital impairment of pulmonary function
7. Severe liver function impairment (alanine aminotransferase [ALAT] 3 x greater than normal value)
8. Severe renal function impairment (creatinine greater than 120 µmol/L), or predisposition for acute renal failure (e.g. any degree of pre-existing renal insufficiency or routine treatment with known nephritic drugs)
9. History of autoimmune haemolytic anaemia
10. History of diabetes mellitus
11. Congestive heart failure New York Heart Association (NYHA) grade III or IV
12. Non-controlled arterial hypertension (systolic blood pressure greater than 160 mmHg and/or diastolic blood pressure greater than 90 mmHg)
13. History of deep vein thrombosis (DVT) or thrombotic complications of IGIV therapy
14. Known to be infected with human immunodeficiency virus (HIV), hepatitis C virus (HCV) or hepatitis B virus (HBV)
15. Presence of any clinically relevant disease or unstable condition beside those concerning study indication at screening which in the opinion of the investigator may interfere with the conduct of the study
16. Treatment with steroids, immunosuppressive or immunomodulatory drugs
17. Planned vaccination during the study period
18. Treatment with any investigational agent within the prior 3 months
19. Known or suspected to abuse alcohol, drugs, psychotropic agents or other chemicals within the last 12 months
20. Pregnant and/or nursing women

Date of first enrolment
01/01/2009

Date of final enrolment
01/06/2010

Locations

Countries of recruitment
Austria

Germany

Poland

Study participating centre
Oberlaaerstrasse 235
Vienna
Austria
1100

Sponsor information

Organisation
Octapharma AG (Switzerland)

Sponsor details
Seidenstrasse 2
Lachen
Switzerland
CH-8853

Sponsor type
Industry

Website
http://www.octapharma.com

ROR
https://ror.org/002k5fe57

Funder(s)

Funder type
Industry

Funder Name
Octapharma AG (Switzerland)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration